

510(k) Summary

JAN 28 2008

Sponsor: Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
Contact: Jonathan M. Gilbert (906) 226-4812

Device Name: Quantum - MIS Cannulated System

Classification : The classification of the subject system is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3070: Pedicle Screw Spinal System. The product codes are MNH, and MNI. The Panel code is 87.

Predicate Device: K041167 – Quantum Spinal System
K070551 – Quantum Spinal System
K072187 – LowTop Spinal Rod System

Intended Use: The Quantum - MIS Cannulated System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and /or lordosis), spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3-S1) with removal of the implants after the attainment of a solid fusion.

Material: Biocompatible alloys in conformance with ASTM Standard Specifications.

Performance Data: Testing per recognized ASTM standards was presented.

Basis of Substantial Equivalence: The Quantum - MIS Cannulated System implants are substantially equivalent to the components of a previously cleared Pioneer spinal system, with similar materials, performance, and indications for use demonstrated.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan M. Gilbert
375 River Park Circle
Marquette, MI 49855

Re: K080026

Trade/Device Name: Quantum-MIS Cannulated System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH
Dated: January 3, 2008
Received: January 8, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Jonathan M. Gilbert

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.0 Indications for Use Statement

Indications for Use

510(k) Number (if known): **K080026**

Device Name: Quantum - MIS Cannulated System

Indications: The Quantum - MIS Cannulated System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, trauma (*i.e.*, fracture or dislocation), deformities or curvatures (*i.e.*, scoliosis, kyphosis, and /or lordosis), spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, this device is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3-S1) with removal of the implants after the attainment of a solid fusion.

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K080026 
MNM